

Application No. 08/499,423

## **REMARKS**

### **I. PRELIMINARY REMARKS**

Claims 1, 3-7, 9-33, 35, 42-44, 46-66, 74-77, 79-88, and 91-97 are pending in the application. Claim 1 is amended in response to an objection.

The Applicants would like to express their appreciation to the Examiner for the opportunity to discuss the present claims with him at the interview of 14 April, 2004. The interview was attended by the undersigned and one of the inventors, Dr. James D. Lewis.

### **II. APPLICANTS' INVENTION**

The present invention relates to a porous polytetrafluoroethylene tube covered by one or more layers of porous polytetrafluoroethylene film, wherein the film-covered tube circumferentially distends from a first circumference upon the application of a circumferentially distending force such as applied by an internal pressure. The film-covered tube exhibits minimal recoil following the removal of the circumferentially distending force. The porous polytetrafluoroethylene film-covered tube has a second circumference that is at least 100% larger than the first circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The porous polytetrafluoroethylene film-covered tube itself provides the circumferential distensibility up to the limit, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The inventive film-covered tube is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilatation of the blood vessel into which it is fitted.

### **III. OBJECTION TO CLAIM 1.**

The claim is objected to because of lack of antecedent basis for "first circumference" on line 5 of the claim. The claim is amended by the deletion of "first" and addition of further language on line 5 defining the word "circumference" that follows the deleted "first." Basis for the amended language is at page 3, line 18 to page 4, line 11.

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**IV. REJECTION OF CLAIMS 1, 3-7, 9-33, 35, 42-44, 46-66, 74-77, 82-88, AND 91-97 VARIOUSLY UNDER 35 USC 102(e) AND 35 USC 103AS BEING UNPATENTABLE OVER SHANNON et al., US 5,641,373, GOLDFARB, US 6,436,135 AND HUGHES et al., US 4,728,328.**

In the Examiner's "Response to Arguments" (page 5) states that because the claimed material is the same material as what is disclosed in the Goldfarb and Shannon references, the tubes of the present application must inherently possess the same functional properties as in the claims. As has been argued previously by the Applicants, there is simply no suggestion in any of the applied references to make a tube that has the claimed functional properties of the present invention (i.e., capable of at least doubling in circumference in response to the application of appropriate pressures and then maintaining a limiting "second" circumference when the applied pressure continues to increase). Nor do any of these references contain any suggestion as to how to provide the lack of recoil possessed by embodiments of the inventive tube when the pressure is removed (recoil being a lack of memory that would result in the circumference of the tube reducing from the second circumference following removal of the internal pressure).

The recited functional properties are the result of processing steps performed on the ePTFE tubes provided with the ePTFE film reinforcing. The inventive tubes differ particularly from the prior art tubes in that they have been processed as taught, resulting in the behavior described by the functional language of the claims. The use of such functional language is well-established, see, for example, *In re Fuetterer*, 138 USPQ 217 (CCPA 1963). The classic citation of *Ex parte Skinner*, 2 USPQ 2d 1788 (BPAI 1986) is particularly relevant when the Examiner asserts that the burden is shifted to the Applicants to show that claimed functional limitation that is critical for establishing novelty is not inherent in the prior art. The Examiner must provide some evidence or scientific reasoning to establish that the functional limitation is an inherent characteristic of the prior art. To simply conclude that the tubes taught by the references are made from the same materials is inadequate in that it is well appreciated in the art of such tubes that their behavioral characteristics are a function of how they are manufactured (i.e., have they been heat-treated?).

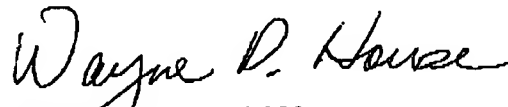
Likewise, there is no basis to conclude that the tube of Goldfarb possesses the claimed lack of recoil characteristics when the only logical conclusion that may be reached on the basis of that reference is that the Goldfarb tube will increase in diameter (and consequently, circumference) on exposure to increasing pressure and will recover to the smaller diameter due to plastic memory when the pressure is removed. It must be appreciated that the present claims

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require lack of appreciable recoil while the conventional ePTFE tube of Goldfarb does indeed (as suggested by the Examiner) recoil. Goldfarb has not been processed with the necessary steps taught by the present invention that prevent recoil, nor does Goldfarb possess the claimed ePTFE film covering.

The Applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,



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